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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/442,542	11/18/1999	LONNIE D SHEA	4100.002000	6026

7590

05/08/2002

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EXAMINER
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KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/08/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/442,542

Applicant(s)

SHEA ET AL.

Examiner

S. Kaushal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 30 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-88 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

In response to applicant's remarks filed on Paper NO. 10, 01/30/02, the restriction requirement sent in an earlier Official Action on Paper NO. 8, 05/02/01 is vacated and a new restriction requirement is issued below:

Claims 89-101 were canceled. Claims 1-88 were pending and were examined in this office action.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, **19, 21-35**, 36-37, 40-68 drawn to a composition and a method of making the composition, comprising a first nucleic acid segment in association with a structural porous matrix, wherein the nucleic acid segment is a DNA molecule encoding a protein, classified in class 435, subclass 320.1.
- II. Claims 1-18, **20**, 36-37, 40-68 drawn to a composition and a method of making the composition, comprising a first nucleic acid segment in association with a structural porous matrix, wherein the nucleic acid segment is an ANTISENSE molecule, classified in class 435, subclass 320.1.
- III. Claims 38-39 are drawn to a composition and a method of making the composition, wherein the composition further comprises a cell population, classified in class 435, subclass 325.

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- IV. Claims 68-73, 75-77, drawn to a method for making genetically engineered cells in-vitro, wherein the genetically engineered cells can be used for a ex-vivo gene therapy procedure, classified in class 424, subclass 93.21.
- V. Claims 68-74, 78-82, **83**, **84**, and **88** are drawn to a method for stimulating bone progenitor cells located with in a bone progenitor tissue site of an animal classified in class 514, subclass 44.
- VI. Claims 68-74, 78-82, and **85** are drawn to a method for stimulating wound healing located with in a wounded tissue site of an animal, classified in class 514, subclass 44.
- VII. Claims 68-74, 78-82, and **86** are drawn to a method for a method for stimulating immune response via targeting APC in an animal, classified in class 514, subclass 44.
- VIII. Claims 68-74, 78-82, and **87** are drawn to a method for a method for inducing cell death in a cell in an animal, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I-III and Groups IV-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition of Group I can be used in vivo or to make the composition of Group III. Furthermore, the composition of Group III can be use to deliver DNA encoding a protein or an antisense molecule in cultured cells. In addition the invention of Group IV is only limited to gene transfer (DNA encoding a protein) in vitro.

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Therefore the composition(s) as claimed are distinct from the methods as claimed and are of separate uses.

Inventions of Group I (*DNA encoding a protein*) and Group II (*antisense*) are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case a DNA molecule encoding a protein or polypeptide of interest is have different modes of operation, different functions, or different effects as compared to an antisense molecule. For example, a DNA molecule would result in the expression of a functional protein whereas the expression of an antisense molecule would inhibits the expression of the protein of interest. Therefore these inventions are distinct and are of separate uses.

Inventions I-II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination of Group III as claimed does not require the particulars of the subcombination as claimed because the composition can be any nucleic acid, and need not to be any of the nucleic acid recited in claims 30-34. The subcombination (Group III) has separate utility such as the composition comprising a cell population could also be used to make recombinant proteins in vitro.

Inventions of Group III and Groups IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition can be used for in vitro protein synthesis or ex-vivo therapy. Therefore the composition as claimed are distinct from the methods as claimed and are of separate uses.

Inventions of Group V-VIII are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Method of stimulating bone progenitor cells for bone healing, repairing cells or fibroblasts for wound healing, stimulating antigen presenting cells for immune response, killing malignant or infected cells have different modes of operation, different functions, or different effects. For example, stimulating bone progenitor cells would promotes the bone formation, whereas the targeting the malignant or infected cells with nucleic acid of encoding death molecules would result in the loss these cells. Furthermore, targeting antigen presenting cells with nucleic acid of interest to generate an immune response is functionally distinct from wound healing which involves cell growth in response to various humoral factors. Therefore, these methods are distinct and are of separate uses.

Invention of Group IV (in-vitro) is distinct from Groups V-VIII (in vivo). Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of Group IV is drawn to a method of making genetically modified cells in-vitro, which can be used for an ex-vivo gene therapy procedure, wherein the invention of Group V-VIII is drawn to a method of in-vivo use. The method of transducing cells in-vivo is distinct from the method of transplanting genetically engineered cells. The transplanted cells include genetically modified cells of xenogenic origin, whereas in-vivo gene transduction includes the cells within the body of the transduced animal. Therefore these inventions are distinct and are of separate uses.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper, the search required for each group is not required for all other groups restriction for examination purposes as indicated is proper.

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Claims 1-18, 36-37 and 40-68 are generic to inventions of Group I and II and will be examined with the elected invention.

Claims 68-73 are generic to Group IV, V, VI, VII and VIII. Claims 73 links Group IV with V, VI, VII and VIII and will be examined with the elected invention.

Claims 78-82 are generic to inventions of Group V, VI, VII and VIII and will be examined with the elected invention.

This application contains claims directed to the following patentably distinct species of the claimed invention of Group I as recited in claims 30-34:

Claims 30 recites a composition wherein the nucleic acid segment encoding a protein that encodes a transcription factor, elongation factor, cell cycle control protein, kinase, phosphatase, DNA repair protein, oncogene, tumor suppressor, angiogenic protein, anti-angiogenic protein, immune response stimulating protein, cell surface receptor, accessory signaling molecule, transport protein, enzyme, anti-bacterial protein or polypeptide, and anti-viral protein or polypeptide.

Claims 31 recites a composition wherein the nucleic acid segment encoding a protein that encodes a neurotransmitter, a growth factor receptor, an interferon, an interleukin, a chemokine and/or a chemotactic factor protein or polypeptide.

If Group I is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that should any of Groups III-VII be elected, and applicant files new set of claims reciting species similar to claim 30-34, an election of species will be required following such amendment.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-

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6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Irem.Yucel can be reached on (703) 305-1998. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Zeta Adams, whose telephone number is (703) 305-3291.

*S. Kaushal*

Patent examiner

*Scott D. Priebe*

SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER